REMARKS

I. PENDING CLAIMS

Claims 1-4 and 8-21 are pending in this application. Claims 1-3 have been allowed. Claims 4 and 8-21 are presently being considered on the merits. Of these, claims 12-14, 17, and 18 have been objected to as dependent on a rejected base claim, but indicated to be otherwise allowable.

II. ANTICIPATION REJECTION OVER MONSON

At page 2 of the Office action, the Examiner has rejected claims 4, 10, 11, 15, 16, and 19 under 35 U.S.C. § 102(b) as anticipated by Monson (U.S. Patent No. 4,863,477). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

In order for an anticipation rejection to be proper, the alleged anticipatory reference must, within its four corners, teach an embodiment containing every element recited in the Applicants' claims. Monson fails in this respect; in fact, Monson uses an approach to inserting intervertebral discs that is diametrically opposed to that recited in Applicants' claims.

Monson discloses an intervertebral disc prosthesis made of synthetic material that is molded to the approximate size and shape of the natural disc that is to be replaced. The method that Monson discloses for implanting his prosthesis includes the steps of:

(1) excising and removing damaged natural disc, including the annulus;

(2) pulling the opposing vertebral endplates away from each other with a retractor in order to create sufficient space to insert the prosthesis;

(3) inserting a rolled-up prosthesis into the space created by retraction;

(4) unrolling the prosthesis; and

(5) inflating the prosthesis with fluid until it conforms to the approximate shape and size of the removed disc material. See column 5, lines 30-61. The retraction of the endplates can then be released. The Monson prosthesis is disclosed to include tiny suction cups that are designed to adhere to the natural, slightly concave surfaces of the vertebral endplates in order to prevent dislocation of the prosthesis. See column 2, lines 59-63.

By stark contrast, claim 4 recites an implantation method wherein the adjacent vertebral endplates are milled to the shape of the prosthesis. Thus, rather than prepare a prosthesis that has a shape corresponding to that of the natural disc, and that therefore mates with the natural shape of the endplates, Applicants' method takes the opposite approach of modifying the intervertebral space to correspond in shape to that of the prosthesis. This has a number of advantages, not the least of which is that the shape factor of the prosthesis and intervertebral space can be engineered to limit motion of the prosthesis shells relative to the vertebrae. In addition, milling of the endplates may provide contact between cancellous bone and porous surfaces of the prosthesis, providing the opportunity for bony ingrowth. Both of these advantages restrain the prosthesis within the intervertebral space without resort to things like miniature suction cups, which are doubtless both difficult and expensive to mold onto a prosthesis.

Because Monson does not teach milling the vertebral endplates, it fails to teach every element of claim 4, and therefore cannot be an anticipatory reference. The Examiner's rejection should therefore be withdrawn.

III. OBVIOUSNESS REJECTION OVER SHEPPARD, MICHELSON

At page 3 of the Office action, the Examiner has rejected claim 8 under 35 U.S.C. § 103(a) as obvious over Sheppard (U.S. Patent No. 4,863,476) in view of Michelson (U.S. Patent No. 5,015,247). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

The Examiner has apparently taken the position that Sheppard discloses an implant that has convex shells capable of motion relative to each other, apparently basing this assertion on the motion of the Sheppard body portions apart as the device is expanded to fit into the intervertebral space. The Examiner also apparently takes the position that the disclosure in Sheppard of inserting the device through a small incision would motivate one of ordinary skill in the art to combine the implant of Sheppard with the implantation method disclosed in Michelson, which also allegedly uses a small incision.

However, Applicants submit that introduction of a prosthesis through a small incision is not sufficient basis for asserting that motivation exists for combining reference teachings, particularly reference teachings as disparate as those of Sheppard and Michelson.

First, in any surgical procedure, the surgeon's goal is to carry out the surgery with as small an incision as is possible. The use of a "small incision" as a common

thread for motivation to combine reference teachings would support combination of virtually any disclosures of any surgical procedures – an untenable result.

Second, Sheppard completely fails to disclose or suggest any modification of the vertebral endplates to accommodate the prosthesis. To the contrary, in column 6, lines 19-29 (the same passage upon which the Examiner apparently relies for the teaching of a "small incision"), Sheppard teaches providing the cylindrical bodies with flattened surfaces to better fit against the vertebral bodies and prevent slippage. Michelson cuts away plugs of bone and cartilage (hardly a "small" incision by any surgeon's definition) in order to introduce his fusion cage into the intervertebral space. Thus, the Examiner is, in effect, asserting that a worker of ordinary skill would have been motivated to implant a prosthetic, disclosed in Sheppard as having a shape modified to fit the natural intervertebral space, using a procedure disclosed in Michelson for introducing a prosthetic into an intervertebral space that has been modified to match the shape of the prosthetic. Applicants respectfully submit that this is incorrect: that the approaches of (1) developing an implant shaped to fit into the natural intervertebral space and (2) modifying the intervertebral space to conform to the shape of the implant are diametrically opposed, and not combinable.

Third, and as discussed in Applicants' previous response, Michelson teaches away from using an implant that can rock. *See* Michelson at column 4, lines 45-55 and at column 10, lines 53-56. *See also*, Applicants' Amendment dated April 5, 2002 at pages 9-11. Given that the Sheppard implant can undergo a rocking motion, there would not have been any motivation for one of ordinary skill in the art to use it in the implantation process of Michelson.

For each of these reasons, the Examiner's conclusion that a worker of ordinary skill in this art would have been motivated to use the implant of Sheppard in the implantation process of Michelson is incorrect. Absent some other motivation for combining the reference teachings, Applicants' respectfully submit that, on this basis alone, the Examiner has failed to establish a *prima facie* case of obviousness of claim 8. However, even if the reference teachings were properly combinable in the manner suggested by the Examiner, there would still be no *prima facie* case of obviousness, because the claimed method would not be obtained.

Claim 8 recites "mounting an intervertebral disc endoprosthesis . . . so that outer surfaces of the . . . endoprosthesis mate with the previously milled bone surfaces and are capable of motion relative to each other." In other words, after the endoprosthesis is mounted, the outer surfaces are capable of movement relative to each other. By contrast, the axial movement of the prosthesis of Sheppard occurs only before the prosthesis is mounted in the intervertebral space. There is no motion of the outer surfaces of the Sheppard prosthesis relative to each other after expansion of the prosthesis is complete.[1]

Applicants respectfully submit that, for each of the reasons set forth above, the Examiner has failed to establish a *prima facie* case of obviousness over Sheppard in view of Michelson, and that this rejection should be withdrawn.

[1] Unless, of course, the prosthetic was inserted in "rocking" mode, in which case there is an explicit teaching away from combination with the Michelson procedure, as described above.

IV. OBVIOUSNESS REJECTION OVER MONSON

At pages 3-4 of the Office action, the Examiner has rejected claims 9, 20, and 21 as obvious under 35 U.S.C. § 103(a) over Monson. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

The deficiencies of Monson have been described in some detail above with respect to the anticipation rejection of claims 4, 10, 11, 15, 16, and 19, and that description is incorporated by reference here. Monson does not teach or suggest forming concave surfaces in adjacent vertebral bodies. As described above, Monson teaches merely removal of damaged disc material and subsequent retraction of the vertebral bodies (without modifying their surfaces) so that a rolled-up, deflated prosthesis can be inserted, unrolled, and inflated to conform to the natural surfaces of the endplates. The Examiner has not provided any explanation of why a worker of ordinary skill in this art would have been motivated to modify the teachings of Monson in such a way as to disregard the explicit requirements of the Monson process and alter the shape of the vertebral endplates. As a result, the Examiner has failed to establish a *prima facie* case of obviousness, and this rejection should be withdrawn.

Applicants submit that this application is in condition for immediate allowance, and an early notification to that effect is earnestly solicited. Further, if any issues remain to be resolved, Applicants request that the Examiner contact the undersigned to arrange for a personal or telephonic interview before issuance of any Advisory Action in this application.

Please charge any additional fees or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,

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